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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
MCKENZIE, THOMAS C

ART UNIT	PAPER NUMBER
1624	15

DATE MAILED: 12/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/534,706	ELLMAN ET AL.	
	Examiner	Art Unit	
	Thomas McKenzie Ph.D.	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-50 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is in response to amendments filed on 10/29/02. Applicants made no amendments to the claims. All claims were previously rejected. This is the third action on the merits. The application concerns some peptide mimetic enzyme inhibitors for Alzheimer's disease treatment.

Response to Amendment

2. Applicants' amendment to the first line of the specification overcomes the objected made in point #3 of the previous office action.

3. The declaration of Dr. Bi under 37 CFR 1.132 filed 10/29/02 is insufficient to overcome the rejection of claims 1-50 based upon lack of utility and lack of enablement for how to use as set forth in the last Office action because: the declaration contains no data but rather allegation of Applicant. Mere allegations are not probative. *In re CHILOWSKY*, 134 USPQ 515, "[i]n this respect they are not only expressions of opinion but incompetent expressions. We have been unable to find in the facts which the affidavits support a basis for deciding that Chilowsky has complied with the requirements of section 112.", *In re LINDELL*, 155 USPQ 521.

A declaration attempting to show that the disclosure is enabling must establish that the person making it is of the appropriate level of skill in the art. In spite of Dr. Bi's medical degree from China, awarded in 1982, the Examiner cannot

find that Dr. Bi has any training or experience in the clinical treatment of Alzheimer's disease in human patients.

A declaration attempting to show that the disclosure is enabling must present facts that are commensurate in scope with the claims, *In re Armbruster* 158 USPQ 152. Such a declaration would have to by a recognized expert in the clinical treatment of all neurodegenerative diseases who is familiar with cathepsin D pharmacology and who would state that it is art-recognized in clinical gerontology, that cathepsin inhibitors are useful for treating such diseases.

Claim Rejections - 35 USC § 112

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 1-50 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well-established utility. Applicants' only assertion of a specific and substantial utility is to treatment of Alzheimer's disease. Wagner (J. Clinical Invest.) in the first sentence of the paragraph spanning both sides of page 1332 makes clear that the *in vivo* evaluation of modulators of β-amyloid production has not been done. In the final sentence Wagner (J. Clinical Invest.) writes "none of the currently available models recapitulate the entire scope of behavioral and pathological features of [Alzheimer's Disease]". Thus, not only have Applicants' compounds never been evaluated for clinical efficacy, no compounds which share

Applicants' mechanism of action have been evaluated for such human efficacy. In addition, there is no demonstration of correlation of *in vitro* data to human efficacy in this area.

5. Claims 1-50 also remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The how to use portion of the statute means that Applicants must teach the skilled practitioner, in this case a physician, how to treat the claimed disease. The rejected claims are drawn to treatment of all neurodegenerative diseases by manipulation of amyloid precursor protein processing and manipulating tau-protein processing using some specified cathepsin D enzyme inhibitors, which as recited reads on the treatment of any and all diseases for which there is no enabling disclosure. This scope of disease treatment is not adequately supported based solely on the testing data provided in the specification at pages 53-55 and 55-59. The specification at pages 62-63 asserts that the compounds are useful for treating all sorts of diseases for which Applicants have provided no empirical support. A recent review of β-amyloid production inhibition, cited previously and dated two years after Applicants' claimed effective filing date, states that use of such

inhibitors is still in the experimental stage and is speculative in nature. Substantiation of use and scope is required when the use is "speculative", "sufficiently unusual", or not provided in the specification, *Ex parte Jovanovics,* 211 USPQ 907, *In re Langer,* 183 USPQ 288, *Hoffman v. Klaus*, 9 USPQ2d 1657, and *Ex parte Powers*, 200 USPQ 925 concerning the type of testing needed to support *in vivo* use claims.

Case law is clear on this point. In an unpredictable art, such as Alzheimer's disease therapy, *in vitro* assays may be used for enablement only if there is a well-established correlation between the assay and clinical efficacy.

The issue in *Ex parte Balzarini* 21 USPQ2d 1892 concerned HIV treatment and the Board of Patent Appeals and Interferences wrote "While the in *vitro* testing performed on these anti-viral compounds appears to be useful as a screening tool in order to determine which of these anti-viral compounds are candidates for further testing to determine if they possess in *vivo* utility, the in *vitro* tests were not predictive of in *vivo* efficacy."

The issue in *Fujikawa v. Wattanasin* 39 USPQ2d 1895 was adequacy of *in vitro* testing of inhibitors of cholesterol biosynthesis and U.S. Court of Appeals Federal Circuit wrote "*in vitro* results, in combination with a known correlation between such in *vitro* results and in *vivo* activity, may be sufficient to establish

practical utility." Such a correlation does not exist in the art of Alzheimer's disease therapy.

In a peripheral issue involving assaying insulin-like growth factor-I ("IGF-I") in *Genentech Inc. v. Chiron Corp.* 55 USPQ2d 1636, U.S. Court of Appeals Federal Circuit wrote "by the critical date, ... [s]pecific binding in an RRA was known by those skilled in the art to be reasonably correlated with the *in vivo* biological activity of IGF-I."

In *Ex parte Bhide* 42 USPQ2d 1441, the Board of Patent Appeals and Interferences wrote "While in *vitro* or in *vivo* tests would not be the only possible way to overcome our basis for questioning applicants' utility, in *vitro* or in *vivo* tests certainly would provide relevant evidence". The issue in the present case is ~~case is~~ not the utility of applicants' compounds, which was at issue in *Ex parte Bhide* 42 USPQ2d 1441, but rather the narrower issue of enablement for claims drawn to the treatment of Alzheimer's disease. Since such a claim is inherently not credible, the standard of proof required for such an assertion must be high.

In a case concerning a DNA sequence encoding a mature human IL-3 protein, *Ex parte Anderson* 30 USPQ2d 1866, the Board of Patent Appeals and Interferences wrote in passing "We question whether one skilled in the art would accept appellants' *in vitro* test as predictive of *in vivo* results and whether one

skilled in the art would know how to use the Pro (8) protein made. ... Should the claims of this application be prosecuted further in a continuing application we urge the examiner to consider the enablement and utility aspects of patentability."

In an anti-tumor application, *Ex parte Aggarwal* 23 USPQ2d 1334, the Board of Patent Appeals and Interferences wrote "there is considerable doubt that those skilled in the art would be willing to accept appellants' in *vitro* tests and in *vivo* tests as established models predictive of utility against tumors in humans. See *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 The examiner had more than adequate reason to doubt the objective truth of the broad statement of utility set forth in appellants' specification."

In the most definitive finding on this issue of the adequacy of *in vitro* assays for clinical claims, *Ex parte Stevens* 16 USPQ2d 1379 the Board of Patent Appeals and Interferences wrote "The examiner's position is based on the supposition that the facts described above evidence a *prima facie* case of nonenablement with regard to the disclosed utility in light of all the applicable legal precedents. Where as here, the disclosed utility is the treatment of cancer, we agree with this supposition. The examiner has cited Ex *parte Busse*, 1 USPQ2d 1908. In that case, the Board of Patent Appeals and Interferences reviewed the relevant prior decisions of its reviewing court. We shall not repeat those citations here. Suffice

it to say that in every cited case the narrow issue involved was whether or not the evidence of record was based on *in vivo* or *in vitro* studies which were generally recognized by those of ordinary skill in the art as being reasonably predictive of success in the practical utility under consideration, i.e., human or, at least, mammalian therapy."

In a vaccine case, *Ex parte Maas* 14 USPQ2d 1762, the Board of Patent Appeals and Interferences wrote "First, although appellants' specification describes certain in *vitro* experiments, there is no correlation on this record between in *vitro* experiments and a practical utility in currently available form for humans or animals. It is not enough to rely on in *vitro* studies where, as here, a person having ordinary skill in the art has no basis for perceiving those studies as constituting recognized screening procedures with clear relevance to utility in humans or animals. The burden is on appellants to establish the significance of the in *vitro* experiments set forth in their specification."

"The factors to be considered [in making an enablement rejection] have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims." *In re*

Rainer, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546.

Determining if any particular compound of formula (I) would be clinically effective would require synthesis of the substrate, preclinical research concerning animal toxicology, scale-up, and formulation, subjecting the compound to human clinical evaluation for safety, efficacy, and dosing, a huge and potentially open-ended degree of experimentation. The direction concerning the clinical use of Applicants' compounds is found in the passage spanning line 13, page 36 to line 33, page 38. This passage specifies that the dose may fall in a 100-fold range but gives no indication of dosing schedule. There are no working examples of treatment of any disease. The state of the art is summarized below. The artisan using Applicants invention would be a gerontologist with a MD degree, board certification in neurology or gerontology, and several years of experience. The predictability in this art was discussed above. The list of diseases to be treated is broad and discussed below in the enablement rejection of point #7.

The utility and enablement rejections for Alzheimer's disease will be considered together. Applicants argue that the declaration of Dr. Bi provides support for both utility and enablement of Applicants' disease treatment claims, that it is art-recognized aspartyl protease inhibitors are clinically efficacious for the

treatment of all "neurodegenerative disorders", and that Wagner (J. Clinical Invest.), cited above, provides strong support for Applicants' claims. This is not persuasive. Firstly, the deficiencies with the Bi declaration are addressed above in point #3. Secondly, assertion is not evidence. What aspartyl protease inhibitor has shown clinical efficacy against any, let alone all "neurodegenerative disorders"? Where is the evidence of such efficacy? Thirdly, the passage from Wagner (J. Clinical Invest.) that Applicants' quote, "might prove fruitful clinical results", show that such clinical use was speculative and not established in 1999.

Search of Medline reveals four articles, dated the last two years, denying any association between cathepsin D, which is the protease that Applicants believe they are inhibiting, and Alzheimer's disease. These articles, Mateo (Am J. Med. Genet.), Crawford (Neurosci. Lett.), Menzer (Am. J. Med. Genet.), and Matsui (Ann. Neurol.) correct an earlier error and are best summarized by the title of Matsui (Ann. Neurol.), "Cathepsin D polymorphism not associated with Alzheimer's disease in Japanese".

Applicants have received patent protection for their compounds. At issue here is further protection for uses of their compounds. In a dissent to *In re MOUREU AND CHOVIN*, 145 USPQ 452, by Judge Smith he wrote "[c]learly as to the claimed chemical compound appellants here have satisfied such a

requirement. They have not claimed a method of treating a disease. Why therefore should they be required to prescribe dosages, methods of administration, etc. on the theory that their invention resides in the use of rather than in the compound itself?" The answer to Judge Smith's question is that the present Applicants are doing exactly that.

6. Claims 1-35 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims would read on modulating APP processing *in vitro*, inhibiting APP processing in mammals with below normal APP processing activity, modulating APP processing inhibition in mammals with normal APP processing activity, or in asymptomatic mammals with up-regulated APP processing activity. The specification fails to teach any benefit to be gained from such actions. Inhibiting APP processing in mammals with below normal APP processing activity on the face of it would appear dangerous. Is extensive experimentation required on the part of a potential infringer to determine if his use of Applicants' inhibitor falls within the limitations of applicants' claim? *In re Kirk and Petrow*, 153 USPQ 48 (CCPA 1967).

As the Supreme Court said in *Brenner v. Manson*, 148 USPQ at 696: "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." As U.S. Court of Customs and Patent Appeals stated *In re Diedrich* 138 USPQ at 130, quoting with approval from the decision of the board: "We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates."

Applicants argue that the declaration of Dr. Bi provides the required enablement. They also argue that use *in vitro* or use in asymptomatic mammals would retard the progression of neurological disorders. This is not persuasive for two reasons. Firstly, the deficiencies with the Bi declaration are addressed above in point #3. Secondly, these assertions of *in vitro* use or use in asymptomatic mammals are not logical. *In vitro* means outside of animals. Since no neurological disorders could occur outside an animal, no use outside an animal

could affect a disease occurring inside the animal. The Examiner admits that administering a compound that shows activity *in vitro* to an animal (*in vivo*) could have such use. However, that is not what the claim says. The claim includes *in vitro* use *per se*.

Asymptomatic mammals include both healthy animals, which will develop a neurological disorder in the future, and healthy animals, which will remain free of neurological disorders. Again why give the drug to the latter group? Since Applicants lack any means of identifying the former group, it is not logical to assert such a use. It is not logical that one can retard the progress of a disease that does not exist in that particular animal.

7. Claims 36-50 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The scope of "neurodegenerative disorders" cannot be deemed enabled. The term "neurodegenerative disorders" covers a broad array of different disorders that have different modes of action and different origins. The term covers such diverse disorders as Alzheimer's Disease; Parkinson's Disease; ALS and variants such as forms of ALS-PDC; Gerstmann-Straussler-Scheinker Disease (GSS); Pick's

Disease; Diffuse Lewy Body Disease; Hallervordon-Spatz disease; progressive familiar myoclonic epilepsy; Corticodentatonigral degeneration; progressive supranuclear palsy (Steele-Richardson-Olszewski); Huntington's disease; more than a dozen dementias collectively called "frontotemporal dementia and Parkinsonism linked to chromosome 17" (FTDP-17); Tourette's syndrome; Shy-Drager syndrome; Friedrich's ataxia and other spinocerebellar degenerations; Olivopontocerebellar atrophy (OPCA); spasmotic torticollis; Striatonigral degeneration; various types of torsion dystonia; certain spinal muscular atrophies, such as Werdnig-Hoffmann and Wohlfart-Kugelberg-Welander; Hereditary spastic paraplegia, Primary lateral sclerosis; peroneal muscular atrophy (Charcot-Marie-Tooth); Creutzfeldt-Jakob Disease (CJD); Hypertrophic interstitial polyneuropathy (Dejerine-Sottas); retinitis pigmentosa; Leber's Disease; and Hypertrophic interstitial polyneuropathy. These exhibit a very broad range of effects and origins. For example, some give progressive dementia without other prominent neurological signs, such as Alzheimer's disease, whereas other dementias have such signs, such as Diffuse Lewy Body Disease. Some give muscular wasting without sensory changes, e.g. ALS, and some do have the sensory changes such as Werdnig-Hoffmann. Some are abnormalities of posture, movement, or speech, such as Striatonigral degeneration, and other are progressive ataxias, such as

OPCA. Some are linked to tau mutations, such as Alzheimer's disease and FTDP-17, and other such as Parkinson's clearly do not. Some affect only vision such as retinitis pigmentosa. Even within those that fall into the same category of effects, there are often striking differences. For example, Alzheimer's disease and Pick's disease both give progressive dementia without other prominent neurological signs. However, the characteristic Alzheimer's neurofibrillary tangles are not seen in Pick's Disease, which has straight fibrils, as opposed to the paired helical filaments of Alzheimer's disease. Pick's Disease gives lobal atrophy, not seen in Alzheimer's disease. There are differences in origins, even with what little is known. Thus, among progressive dementias, CJD is definitely caused by an infectious agent; so far as can be determined, this is not so for Huntington's disease. Even among the hereditary disorders, the origins are different. Thus, FTDP-17 comes from chromosome 17, Huntington's disease from 4, and the neurodegenerative disorder that people with Down's syndrome develop later in life is presumably connected in some way to 21.

The great majority of these have no treatment at all, and of those that do, none or virtually none have been treated with such inhibitors as are disclosed here. The great diversity of diseases falling within the "neurodegenerative disorder" category means that it is contrary to medical understanding that any agent (let

alone a genus of trillions of compounds) could be generally effective against such diseases. The intractability of these disorders is clear evidence that the skill level in this art is low relative to the difficulty of the task. Further, what little success there has been does not point in this direction. Thus, what very few treatments that the massive research effort on Alzheimer's disease has produced are means of providing acetylcholinesterase inhibition, unrelated to the mechanism of action in this case.

The scope of "treating ... cognition disorders" cannot be deemed enabled. The term "cognition" covers uses on a broad array of human mental states. It would encompass both normal subjects as well as patients suffering from various disorders that have different modes of action and different origins. These disorders would include developmental dyslexia, closed head injury, schizophrenia, Alzheimer's disease, mild cognitive disorder, sub-clinical senescent cognitive disorder, and depression. Most of these disorders have no effective treatment at all, and none have been treated with such inhibitors as are disclosed here.

The scope of "treating ... Alzheimer's disease" cannot be deemed enabled for reasons cited above in point #4. Additionally, there is no cure for the different types of Alzheimer's diseases and none have been treated with such amyloid synthesis modulators as are disclosed here. Augelli-Szafran (Ann. Reports Med.

Chem.) writes in the final two sentences of the first paragraph on page 28, "question that remains to be answered is whether compounds that inhibit [amyloid β] production ... will impede the pathogenesis of [Alzheimer's Disease]." Thus, as of 1997 clinical effacay of compounds with Applicants' mechanism of action had not been established.

The intractability of Alzheimer's disease is clear evidence that the skill level in this art is low relative to the difficulty of the task and not sufficient to enable treatment with inhibitors of this sort. Further, what little success there has been does not point in this direction. Thus, what very few treatments that the massive research effort on Alzheimer's diseases has produced are means of providing acetylcholinesterase inhibition, unrelated to the mechanism of action in this case.

The scope of "treatment or preventing ..... Parkinson's diseases" cannot be deemed enabled. A recent review "Developments in the Treatment of Parkinson's Disease" mentions levodopa, catechol-O-methyl transferase inhibitors, dopamine agonists, muscarinic antagonists, and N-methyl-D-aspartate receptor antagonists as possible therapeutic modalities for Parkinson's disease. The review does not mention such inhibitors as are disclosed here.

Applicants argue that the declaration of Dr. Bi overcomes the indefiniteness and argue that they have met the threshold of required utility. This is not

persusive. Firstly, the Bi decleration is discussed above. Secondly, this is an enablement rejection under 35 U.S.C. 112, first paragraph not a utility rejection made under 35 U.S.C. 101. The standards are different (and higher) for enablement.

8. Claims 1-10, 13-28, 31-48, and 50 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants repeatedly claim "substituted alkyl", "substituted aryl", and "substituted heteroaryl". These terms are defined in the specification in lines 9-15, page 11, lines 25-32, page 11, and lines 13-22, page 13 respectively. The definitions use open language "such as". Are there any limitations as to which substituents are claimed? How is the public to understand the metes and bounds of the claims? What exactly is the structure of the compounds, whose use Applicants claim? The Examiner suggests adding to the claims the specific substituents that may be attached to alkyl, aryl, or heteroaryl. Alternatively, Applicants can amend the specification to remove the open terms from the passages cited.

Applicants argue that the terms "substituted alkyl" *etc.* are in routine use, that the terms are defined in the specification, and that no undue experimentation would be required to determine in any particular substituted alkyl group etc would

be active. This is not persusive. Firstly, the art-reconized meaning is that a hydrogen atom has been removed from an alkyl radical and replaced by "[a]n atom or radical", Hawley (The Condensed Chemical Dictonary). There are no limiations placed on the radicals added. The phrase substituted alkyl group will have different meanins in differet patents, depending upon how it is defined in the specification of the particular patent. Applicants fail to cite any generally accepted list of possible substituents and their assertion is not evidence. The indefiniteness remains despite what was allowed in another case. The U.S. Court of Customs and Patent Appeals wrote *In re Giolito* 188 USPQ 645: "We reject appellants' argument that the instant claims are allowable because similar claims have been allowed in a patent. It is immaterial whether similar claims have been allowed to others. See *In re Margaroli,* 50 CCPA 1400, 318 F.2d 348, 138 USPQ 158 (1963); *In re Wright*, 45 CCPA 1005, 256 F.2d 583, 118 USPQ 287 (1958); *In re Launder*, 41 CCPA 887, 212 F.2d 603, 101 USPQ 391 (1954)". Secondly, the open language in the specifcation is addressed above. Thus, the terms are not properly defined in the specification. Thirdly, this is an indefiniteness, not an enablement rejection. Thus, the nature of the experimentation is not an issue.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for

reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (703) 308-9806. The FAX number for after final amendments is (703) 872-9307. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mukund Shah can be reached on (703) 308-4716. Please direct general inquiries or any inquiry relating to the status of this application to the receptionist whose telephone number is (703) 308-1235.

Mukund Shah
Supervisory Patent Examiner
Art Unit 1624

TCMcK
December 27, 2002

E Bernhardt (for SPE Shah)

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